

Application No. 10/701,768
Amendment "B" dated December 7, 2004
Reply in Office Action mailed July 26, 2004

REMARKS

Applicants and Applicants' attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on November 30, 2004. Reconsideration and allowance of the above-identified application are now respectfully requested. Claims 1-33 are pending, wherein claims 1-3, 12, 19, 21 and 23-26 have been amended.

As proposed during the Examiner Interview, Applicants have amended the claims to recite specific structural features to better distinguish between the claimed "non-custom" pre-formed dental trays according to the invention and the customized dental trays disclosed in the cited art. The independent claims have been amended to specify that the "side walls" of the dental tray "are substantially devoid of structures corresponding to the size and shape of a person's unique dentition so that the dental tray is designed to comfortably fit over a plurality of differently-sized dental arches corresponding to different people".

Support for this limitation is shown in the drawings, e.g., Figures 1A and 1B, which show front and rear side walls that have textured inner surfaces but no indentations of any kind corresponding to the size and shape of a person's unique dentition, as are found in customized dental trays. Further support is found in the background section, which describes how customized dental trays can be formed either by vacuum forming a dental tray from a stone model of a person's teeth or forming a tray directly using a person's teeth as the template. Application, ¶¶ 3-6. In either case, the customization process yields a dental tray that is known by those of skill in the art to have indentations that correspond to the unique dentition of a particular person. See U.S. Patent No. 6,036,943 to Fischer; U.S. Patent No. 5,562,449 to Jacobs et al. In contrast, the inventive dental trays are described in terms of their ability to universally fit a variety of differently sized and shaped dental arches and teeth of different people precisely because they are not customized (i.e., include no structures corresponding to the size and shape of any one person's unique dentition). Application, ¶¶ 11, 33.

It is the thinness and flexibility of the dental tray walls, rather than including indentations corresponding to a particular person's teeth, that result in comfort to the user. Application, ¶ 16. In view of this, the independent claims were further amended to recite that "the tray can at least partially conform to the person's teeth during use in order to approximate the comfort and fit of a custom dental tray without the need to formally customize the tray", thus expressly excluding

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custom trays (like those disclosed in Fischer) from within the scope of the claims. Support for this limitation is found in the application in paragraphs 10 and 16.

The major benefit of providing pre-formed, non-custom dental trays having thin walls for approximating the comfort of a custom tray is the elimination of the customization procedure. Application, ¶ 22. Customized dental trays are typically obtained from a dentist at considerable cost, time and hassle. Application, ¶¶ 3-4. Boil-and-bite trays, on the other hand, tend to be thick and bulky. Application, ¶¶ 5-6. The non-customized dental trays according to the invention can be used immediately without customizing them to the user's teeth. In addition, they are thin-walled and comfortable in order to approximate the comfort and fit of a custom tray.

One way to better understand the difference between non-custom and custom trays is to consider that dentition is so varied and unique among different people that forensic experts can use dental records to identify dead people that are otherwise unrecognizable (e.g., because of fire). That means that a dental tray customized to exactly fit one person is not likely to exactly, let alone comfortably, fit another person. For this reason, customized dental trays cannot be used by different people having differently-sized and shaped teeth. In contrast, the claimed non-custom dental trays are able to fit a variety of differently sized and shaped teeth of different people. Thus, the terms "custom" and "non-custom" go beyond merely describing the method of making such trays, but actually define mutually exclusive tray types — one that includes indentations that correspond to the size and shape of a particular person's teeth and one that lacks such structural features.

Because the term "non-custom" dental tray excludes the "custom" dental trays made according to Fischer, particularly in view of the additional limitations added to the claims, Applicants submit that Fischer neither teaches nor suggests the use of non-custom dental trays, either alone or pre-filled with a dental treatment composition. According to the Office Action, p. 2, "Fischer does not show a 'non-custom' tray." For this reason, the Office Action combines Fischer with U.S. Patent No. 4,138,814 to Weitzman. The Office Action reasons that the combined teachings of Fischer, which teaches a thin-walled, custom tray, and Weitzman, which teaches a thick-walled, non-custom tray, renders obvious a thin-walled, non-custom tray.

The problem with this reasoning is at least two-fold. First, Weitzman teaches the importance of providing a non-custom tray that provides a "snug seal between the edges and

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walls of the tray and the adjacent periodontal tissue and teeth". Col. 2, lines 10-12. This snug fit is provided, at least in part, by the enlarged perimeter flange portion 14, which is more clearly shown in Figures 3 and 4. Col. 3, lines 34-43. Weitzman describes the "snug engagement of the applicator tray with the gum and teeth surfaces" as "producing thereby the beneficial results hereinbefore described", thereby showing that "snug fit" or "snug engagement" of a dental tray is critical to the invention of Weitzman. Col. 3, lines 41-44. Moreover, the Weitzman tray is sufficiently thick as to also be usable as an athletic mouth guard that "cushions the teeth from the consequences of severe impacts." Col. 4, lines 1-9 (emphasis added). Applicants note that in order for a mouthguard to cushion teeth from "severe impacts" it must be thick-walled (*i.e.*, typically 3-5 mm according to articles that can be readily found on the Internet).

In view of the fact that Weitzman teaches the importance of a tray that is able to provide "snug engagement" with the gums and teeth and that is inherently thick enough to cushion the user's teeth from "severe impacts", Applicants submit that Weitzman teaches away from thin-walled dental trays (*i.e.*, that have a wall thickness of less than about 1 mm). Indeed, the present application clearly distinguishes over sports mouthguards (like those of Weitzman), which are known to be thick and bulky. Application, ¶¶ 5-6.

Second, because Weitzman teaches the importance of providing a tray that provides "snug engagement" and that is sufficiently thick to cushion teeth from severe blows, Weitzman leads away from the alleged combination with Fischer, which discloses thin-walled, custom trays that are specifically designed so as to "exert little or no significant mechanical pressure on a person's teeth or gums". Col. 5, lines 1-2. Moreover, the background section of Fischer teaches the drawbacks of dental trays that "provide a liquid-tight seal over the person's gums" because such trays "can result in significant discomfort". Col. 1, lines 60 – col. 2, line 4. Because Fischer teaches the importance of providing a tray that exerts "little or no significant mechanical pressure" and also disparages trays that provide a "liquid-tight seal" because they cause "significant discomfort", but because Weitzman teaches the criticality of providing a tray that is makes "snug engagement" with the teeth and gums, Applicants submit that one of skill in the art would not have been motivated to combine the teachings of Fischer and Weitzman.

In conclusion, because each of the claim rejections rely on the combination of Fischer and Weitzman, but because one of skill in the art would not have been motivated to combine the

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teachings of these references (since they mutually teach away from each other), Applicants submit that the claims as amended are believed to be patentable over the art of record.

During the Examiner Interview, the Examiner mentioned that U.S. Patent No. 6,096,328 to Sagel et al. discloses a "non-custom tray". While it may be argued that the whitening strip of Sagel et al., which is initially in the form of a flat sheet prior to use, temporarily forms a "dental tray" when placed over and adhered to a user's teeth by the whitening agent, it is clear that this "strip" does not constitute "a pre-shaped, non-custom dental tray suitable for placement over at least one of a person's upper or lower dental arches" (i.e., that is able to retain the shape of a dental tray even before being placed over a person's teeth).

In view of the foregoing, Applicants submit that the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney (e.g., if the Examiner concludes that the claims of this application raise an obviousness-type double patenting issue relative to the parent application, Applicants invite the Examiner to call the undersigned attorney so that a terminal disclaimer can be promptly filed).

Dated this 7th day of December 2004.

Respectfully submitted,



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